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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,715	01/14/2002	Yoshinobu Kiso	46/225	8223
20736	7590	05/24/2004	EXAMINER	
MANELLI DENISON & SELTER 2000 M STREET NW SUITE 700 WASHINGTON, DC 20036-3307			WANG, SHENGJUN	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 05/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,715

Applicant(s)

KISO ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4 and 6-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8 is/are allowed.
- 6) ☒ Claim(s) 4, 6, 7, 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 12, 2004 has been entered.

Claim Rejection 35 U.S.C. 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claim 6,7 and 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Asami et al. (EP 0,770,385, IDS MR).

3. Asami et al. teaches an anti-stress composition comprising astaxanthin and the method of using the same for treating stress. See the abstract and the claims, page 5, lines 41-55. Asami et al. further discloses that it is known in the art that stress cause somatic disorder as well as neurosis and depression. Stress destroys the ability of maintain homeostasis by the body. Conventional treatment of stress includes anti-anxiety agents and sleeping pills. See page 2, lines 9-14. Note, by definition, stress is reactions of the body to forces of a deleterious nature, infections, and various abnormal states that tend to disturb its normal physiologic equilibrium

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(homeostasis). (see Stedman's Medical dictionary). Normal circadian rhythm is part of homeostasis, and disturbance of circadian rhythm is a type of stress.

4. Asami et al. does not teach expressly to employ the astaxanthin containing composition for treating patient having disturbance of circadian rhythm.

5. However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the astaxanthin containing composition for treating patient having disturbance of circadian rhythm because disturbance of circadian rhythm is a well-known type of stress. One of ordinary skill in the art would have reasonably expected that the astaxanthin-containing composition to be beneficial for patient having disturbance of circadian rhythm because the composition is known for anti-stressing. Furthermore, a composition useful for treating stress would have been reasonably expected to be useful for alleviating symptoms caused by stress, such as reduced homeostasis, or sleep disorder. As to claim 9, the recitation "suppressing degradation of in vivo melatonin" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Asami et al. (EP 0,770,385, IDS MR) in view of Pierpaoli et al. (WO 88/07367).

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7. Asami et al. teaches an anti-stress composition comprising astaxanthin and the method of using the same for treating stress. See the abstract and the claims, page 5, lines 41-55. Asami et al. further discloses that it is known in the art that stress cause somatic disorder as well as neurosis and depression. Stress destroys the ability of maintain homeostasis by the body. Conventional treatment of stress includes anti-anxiety agents and sleeping pills. See page 2, lines 9-14. Note, by definition, stress is reactions of the body to forces of a deleterious nature, infections, and various abnormal states that tend to disturb its normal physiologic equilibrium (homeostasis). (see Stedman's Medical dictionary). Normal circadian rhythm is part of homeostasis, and disturbance of circadian rhythm is a type of stress.

8. Asami et al. does not teach expressly the composition also comprising melatonin, or the employment of such composition for treating patient with disturbance of circadian rhythm.

9. However, Pierpaoli teaches that melatonin or its derivatives are known to be useful for treating patients having stress or acute anxiety as well as for the enhancement of immune resistance.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a composition comprising both melatonin and astaxanthin for treating patients having stress or the symptoms caused by stress, including disturbance of circadian rhythm and symptoms caused by the disturbance of circadian rhythm.

A person of ordinary skill in the art would have been motivated to make a composition comprising both melatonin and astaxanthin for treating patients having stress or the symptoms caused by stress including disturbance of circadian rhythm and symptoms caused by the

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disturbance of circadian rhythm because it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus, the claimed invention which is a combination of two anti-stress agents sets forth prima facie obvious subject matter. See In re Kerkhoven, 205 USPQ 1069. Further, disturbance of circadian rhythm, or sleep disorder is a well-known type of stress, e.g., it is known to treat stress with sleep pill.

Response to the Arguments

Applicants' amendments and remarks submitted October 14, 2003 have been fully considered. It is persuasive with respect to the synergistic effect, and therefore, claim 8 was found allowable. But the other claims are properly rejected as they are not commensurate with the scope of the unexpected results.

With respect to claims 6, 7, and 9, applicants argue that Asami does not teach the particular experimentations disclosed herein, and therefor, the claimed invention would have not been obvious over Asami. These arguments are not persuasive. As discussed above, a patient with distress is likely to have disturbed circadian rhythm, and disturbed circadian rhythm is a kind of stress.

As to claim 4, note the claims must be commensurate in the scope with any evidence of unexpected results. See MPEP 716.02 (d). Claim 4 does not recite the amounts of each ingredient, which are critical for the synergistic effect.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang

May 18, 2004